

FIRST REGULAR SESSION
HOUSE COMMITTEE SUBSTITUTE FOR
HOUSE BILL NO. 816
98TH GENERAL ASSEMBLY

1926H.03C

D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal section 195.015 as enacted by senate bill nos. 215 & 58, eighty-fifth general assembly, first regular session, and to enact in lieu thereof seven new sections relating to a prescription drug monitoring program, with penalty provisions and a referendum clause.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Section 195.015 as enacted by senate bill nos. 215 & 58, eighty-fifth general assembly, first regular session, is repealed and seven new sections enacted in lieu thereof, to be known as sections 195.015, 195.450, 195.453, 195.456, 195.459, 195.462, and 195.465, to read as follows:

195.015. 1. The department of health and senior services shall administer sections 195.005 to [195.425] **195.465** and may add substances to the schedules after public notice and hearing. In making a determination regarding a substance, the department of health and senior services shall consider the following:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under sections 195.005 to [195.425] **195.465**.

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

15 2. After considering the factors enumerated in subsection 1 of this section the department
16 of health and senior services shall make findings with respect thereto and issue a rule controlling
17 the substance if it finds the substance has a potential for abuse.

18 3. If the department of health and senior services designates a substance as an immediate
19 precursor, substances which are precursors of the controlled precursor shall not be subject to
20 control solely because they are precursors of the controlled precursor.

21 4. If any substance is designated, rescheduled, or deleted as a controlled substance under
22 federal law and notice thereof is given to the department of health and senior services, the
23 department of health and senior services shall similarly control the substance under sections
24 195.005 to [195.425] **195.465** after the expiration of thirty days from publication in the federal
25 register of a final order designating a substance as a controlled substance or rescheduling or
26 deleting a substance, unless within that thirty-day period, the department of health and senior
27 services objects to inclusion, rescheduling, or deletion. In that case, the department of health and
28 senior services shall publish the reasons for objection and afford all interested parties an
29 opportunity to be heard. At the conclusion of the hearing, the department of health and senior
30 services shall publish its decision, which shall be final unless altered by statute. Upon
31 publication of objection to inclusion, rescheduling or deletion under sections 195.005 to
32 [195.425] **195.465** by the department of health and senior services, control under sections
33 195.005 to [195.425] **195.465** is stayed as to the substance in question until the department of
34 health and senior services publishes its decision.

35 5. The department of health and senior services shall exclude any nonnarcotic substance
36 from a schedule if such substance may, under the federal Food, Drug, and Cosmetic Act and the
37 law of this state, be lawfully sold over the counter without a prescription.

38 6. The department of health and senior services shall prepare a list of all drugs falling
39 within the purview of controlled substances. Upon preparation, a copy of the list shall be filed
40 in the office of the secretary of state.

195.450. 1. Sections 195.450 to 195.465 shall be known and may be cited as the
2 **"Prescription Drug Monitoring Program Act".**

3 **2. As used in sections 195.450 to 195.465, the following terms mean:**

4 **(1) "Controlled substance", the same meaning given such term in section 195.010;**

5 **(2) "Department", the department of health and senior services;**

6 **(3) "Dispenser", a person who delivers a Schedule II, III, or IV controlled**
7 **substance to the ultimate user, but does not include:**

8 **(a) A hospital, as defined in section 197.020, that distributes such substances for the**
9 **purpose of inpatient care or dispenses prescriptions for controlled substances at the time**
10 **of discharge from such facility;**

11 (b) A practitioner or other authorized person who administers such a substance;
12 or

13 (c) A wholesale distributor of a Schedule II, III, or IV controlled substance;

14 (4) "Patient", a person who is the ultimate user of a drug for whom a prescription
15 is issued or for whom a drug is dispensed, except that patient shall not include a hospice
16 patient enrolled in a Medicare-certified hospice program who has controlled substances
17 dispensed to him or her by such hospice program;

18 (5) "Schedule II, III, or IV controlled substance", a controlled substance that is
19 listed in Schedule II, III, or IV of the schedules provided under this chapter or the federal
20 Controlled Substances Act, 21 U.S.C. Section 812.

21 3. Notwithstanding any other law to the contrary, the provisions of sections 195.450
22 to 195.465 shall not apply to persons licensed under chapter 340.

 195.453. 1. The department of health and senior services shall establish and
2 maintain a program for the monitoring of prescribing and dispensing of all Schedule II,
3 III, and IV controlled substances by all professionals licensed to prescribe or dispense such
4 substances in this state. The department may apply for any available grants and may
5 accept any gifts, grants, or donations to develop and maintain the program. All funding
6 for the prescription drug monitoring program may be provided exclusively by gifts, grants,
7 and donations.

8 2. Each dispenser shall submit to the department by electronic means information
9 regarding each dispensation of a drug included in subsection 1 of this section. The
10 information submitted for each dispensation shall include, but not be limited to:

11 (1) The dispenser's federal Drug Enforcement Administration (DEA) number;

12 (2) The date of the dispensation;

13 (3) If there is a prescription:

14 (a) The prescription number;

15 (b) Whether the prescription is new or a refill;

16 (c) The prescriber's DEA or National Provider Identifier (NPI) number;

17 (d) The date the prescription is issued by the prescriber; and

18 (e) The source of payment for the prescription;

19 (4) The name and the National Drug Code (NDC) for the drug dispensed;

20 (5) The number of days' supply of the drug;

21 (6) The quantity dispensed;

22 (7) The patient identification number including, but not limited to, any one of the
23 following:

24 (a) The patient's driver's license number;

- 25 (b) The patient's government-issued identification number; or
26 (c) The patient's insurance cardholder identification number;
27 (8) The patient's name, address, and date of birth.

28 3. Each dispenser shall submit the information in accordance with transmission
29 standards established by the American Society for Automation in Pharmacy, or any
30 successor organization, and shall report data within seven days.

31 4. (1) The department may issue a waiver to a dispenser who is unable to submit
32 dispensation information by electronic means. Such waiver may permit the dispenser to
33 submit dispensation information by paper form or other means, provided all information
34 required in subsection 2 of this section is submitted in such alternative format.

35 (2) The department may grant an extension to dispensers who are temporarily
36 unable to electronically submit the dispensation information required in subsection 2 of
37 this section in accordance with the time frame established in subsection 3 of this section
38 due to unforeseen circumstances. If an extension is granted, dispensers shall be responsible
39 for reporting the required data in a subsequent file.

40 5. The department shall reimburse each dispenser for the transmission fees and
41 other direct costs of transmitting the information required by this section.

195.456. 1. Dispensation information submitted to the department shall be
2 confidential and not subject to public disclosure under chapter 610 except as provided in
3 subsections 3 to 5 of this section.

4 2. The department shall maintain procedures to ensure that the privacy and
5 confidentiality of patients and personal information collected, recorded, transmitted, and
6 maintained is not disclosed to persons except as provided in subsections 3 to 5 of this
7 section.

8 3. The department shall review the dispensation information and, if there is
9 probable cause to believe a violation of law or breach of professional standards may have
10 occurred, the department shall notify the appropriate law enforcement or professional
11 licensing, certification, or regulatory agency or entity, and provide dispensation
12 information required for an investigation.

13 4. The department may provide data in the prescription drug monitoring program
14 to the following:

15 (1) Persons, both in-state and out-of-state, authorized to prescribe or dispense
16 controlled substances for the purpose of providing medical or pharmaceutical care for
17 their patients;

18 (2) An individual who requests his or her own dispensation monitoring information
19 in accordance with state law;

20 (3) The state board of pharmacy;

21 (4) Any state board charged with regulating a professional who has the authority
22 to prescribe or dispense controlled substances that requests data related to a specific
23 professional under the authority of that board;

24 (5) Local, state, and federal law enforcement or prosecutorial officials, both in-state
25 and out-of-state engaged in the administration, investigation, or enforcement of the laws
26 governing licit drugs based on a specific case and under a subpoena or court order;

27 (6) The family support division within the department of social services regarding
28 MO HealthNet program recipients;

29 (7) A judge or other judicial authority under a subpoena or court order;

30 (8) Personnel of the department of health and senior services for the administration
31 and enforcement of sections 195.450 to 195.465; and

32 (9) Other state prescription drug monitoring programs through InterConnect or
33 its successor program.

34 5. The department may provide data to public or private entities for statistical,
35 research, or educational purposes after removing information that could be used to identify
36 individual patients, prescribers, dispensers, or persons who received dispensations from
37 dispensers.

38 6. Nothing in sections 195.450 to 195.465 shall be construed to require a pharmacist
39 or prescriber to obtain information about a patient from the database. A pharmacist or
40 prescriber shall not be held liable for damages to any person in any civil action for injury,
41 death, or loss to person or property on the basis that the pharmacist or prescriber did or
42 did not seek or obtain information from the database.

 195.459. The department is authorized to contract with any other agency of this
2 state or any other state, with a private vendor, or any state government that currently runs
3 a prescription drug monitoring program. Any contractor shall comply with the provisions
4 regarding confidentiality of prescription information in section 195.456.

 195.462. The department shall promulgate rules setting forth the procedures and
2 methods of implementing sections 195.450 to 195.465. Any rule or portion of a rule, as that
3 term is defined in section 536.010, that is created under the authority delegated in this
4 section shall become effective only if it complies with and is subject to all of the provisions
5 of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
6 nonseverable, and if any of the powers vested with the general assembly pursuant to
7 chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are
8 subsequently held unconstitutional, then the grant of rulemaking authority and any rule
9 proposed or adopted after August 28, 2015, shall be invalid and void.

195.465. 1. A dispenser who knowingly fails to submit dispensation monitoring information to the department as required in sections 195.450 to 195.465 or knowingly submits the incorrect dispensation information shall be subject to an administrative penalty in the amount of one hundred dollars for each violation. The department of health and senior services shall promulgate rules and regulations for the assessment of administrative penalties. Any penalty shall be assessed through an order issued by the director of the department. Any person subject to an administrative penalty may appeal to the administrative hearing commission under the provisions of chapter 621.

2. A person authorized to have dispensation monitoring information under sections 195.450 to 195.465 who knowingly discloses such information in violation of sections 195.450 to 195.465 or who uses such information in a manner and for a purpose in violation of sections 195.450 to 195.465 is guilty of a class A misdemeanor.

Section B. Section A of this act is hereby submitted to the qualified voters of this state for approval or rejection at an election which is hereby ordered and which shall be held and conducted on the Tuesday immediately following the first Monday in November, 2016, or at a special election to be called by the governor for that purpose, pursuant to the laws and constitutional provisions of this state applicable to general elections and the submission of referendum measures by initiative petition, and it shall become effective when approved by a majority of the votes cast thereon at such election and not otherwise.

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